REMARKS

Applicant respectfully requests reconsideration. Claims 28-47 were previously pending in this application. Claim 28 is amended herein. Claims 29, 30, and 36 are canceled The limitations of claims 29, 30 and 36 have been added to claim 28. As a result, claims 28 (in part), 31-33, 35, 37, 39, 40 (in part), and 42-47 are still pending for examination with claim 28 being an independent claim. No new matter has been added.

Claim Objections

Claim 28 has been objected to because of a typographical error. Claim 28 has been amended to delete the "s" at the end of "oligonucleotides". It is believed that the rejection should be withdrawn.

Rejection Under 35 U.S.C. 112

Claims 28-33, 35, 36 (in part) 37, 39, 40 (in part) and 42-47, have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

The office action asserts that the in vitro and in vivo data presented in the specification is not adequate to support and does not correlate with a treatment for an immune system deficiency. Several reasons are presented in support of the rejection, each of which is addressed by applicant below.

The correlation between the data in the specification and the treatment of "primary immune system deficiencies" is discussed. The office action asserts that primary immune system deficiencies have an absence or reduced number of T cells or mature B cells and that one would not expect a CpG ODN to work in the absence of functioning B and T cells. The data in the specification not only establishes that CpG oligonucleotides are able to activate B cells but that they induce expression of IL-6, IL-12 and IFN-gamma as well as stimulate NK cell activity. A conclusion that CpG ODN would not be useful in the treatment of a disease that has reduced B cells is not sufficient to support a lack of enablement. CpG oligonucleotides produce an altered immune profile, as asserted in the specification, not just a single cell type.

It is also stated in the Office Action that the treatment and prevention of parasitic infection, such as malarial infection, is unpredictable because the parasite hides within a cell. Applicants attach a paper by Gramzinski et al (Infect and Immunity v. 69, March 2001, p. 1643) that describes the use of CpG ODN to prevent malarial infection in mice. It was determined that the ability of CpG ODN to confer this protection was dependent on the ability to induce IL-12 and IFN-gamma. The teachings of Gramzinski et al are consistent with the teachings of the specification. Jeamwattanalert et al (Clin Vaccine Immunol. 2007 Apr;14(4):342-7) describes a study which involved immunization of mice against a malarial antigen using CpG ODN as an adjuvant. It is concluded in the paper that long-lasting protective immune response to the 19-kilodalton carboxy-terminal fragment of Plasmodium yoelii merozoite surface protein 1 (MSP1) in mice is achieved in the presence of a CpG ODN and Montanide ISA51 adjuvant.

It is further stated in the Office Action that a correlation was established between NK cell activation and IFN inducement and the treatment of tumors by Kataoka, supporting enablement of a treatment for cancer. However, the Examiner questions whether a CpG ODN is useful as a vaccine to prevent all forms of cancer or tumors. The data presented in the specification demonstrated that CpG ODN induce cytokine production and activate immune cells such as NK cells. The response contributes to an immune system attack on the cancer which may be helpful in preventing further progression. Several references have examined the use of CpG vaccines in cancer models. For instance a 2007 review article by Krieg (J Clin Investigation, 2007, v 117, p. 1184) describes studies including human clinical trials using CpG in combination with vaccines in cancer. Sfondrini et al (FASEB 2002 v. 16, p. 1759) describes the prevention of spontaneous mammary adenocarcinoma in mice by CpG ODN.

The Examiner has cited Gura et al (Science v 270 p. 575, 1995) for the teaching that ODN may cause severe side effects in animals. The issue of whether a drug is safe and has no side effects in not an appropriate test for enablement. MPEP2164.01(c). "The applicant need not demonstrate that the invention is completely safe." In fact, one cannot possibly determine the parameters of safety without a controlled clinical trial, and it is well established that a clinical trial is not required for enablement.

In addition, Applicants point out that Several Phase I and II studies have been performed in humans to date. For instance, subcutaneous administration has been performed in humans for a cancer trial. The data are described in Kim et al., Blood, volume 4, issue 11, abstract # 743, Nov. 16, 2004 (copy enclosed with previously filed IDS). Toxic effects that would halt further human trials were not observed, even though the patients were provided CpG oligonucleotides in very aggressive doses. The abstract concludes that "weekly doses up to 0.36 mg/kg have been well tolerated." This clinical trial demonstrates that CpG oligonucleotides have been administered to humans and were well tolerated.

Rejection Under 35 U.S.C. 102

Claims 28, 29, 30, 37, 42, 43, 44, 45, 46 and 47 have been rejected under 35 U.S.C. 102(b) as being anticipated by Draper et al. 1991, WO 91/12811 as evidenced by Gura, Science vol. 270, p. 575-577, 1995.

Although applicant disagrees with the rejection, the limitations of claim 36 have now been incorporated into the independent claim 28 in order to advance prosecution. Claim 36 was not rejected under 35 U.S.C. 102 in view of Draper. Thus it requested that the rejection be withdrawn.

Claims 28, 29, 30, 31, 32, 37, 39, 40 (in part), 42, 43, 44 and 45-47 have been rejected under 35 U.S.C. 102(e) as being anticipated by Hutcherson et al. US 5,723,335 1998 (continuation of serial no. 217,988, March 25, 1994) as evidenced by Gura Science vol. 270, p. 575-577, 1995.

Although applicant disagrees with the rejection, the limitations of claim 36 have now been incorporated into the independent claim 28 in order to advance prosecution. Claim 36 was not rejected under 35 U.S.C. 102 in view of Hutcherson. Thus it requested that the rejection be withdrawn.

Double Patenting Rejection

Claims 28-33, 35, 36 (in part), 37, 39, 40 (in part) 42, 43 and 44-47 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 28-37, 38-39, 40, 42, 43-46 of co-pending Application No. 10/787,737.

Applicants elect to defer substantive rebuttal of the rejection until such time as the cited application is allowed.

Claims 28-31, 32-33, 35, 37, 40 (in part) and 42-46 have been provisionally rejected on the ground of non-statutory obviousness –type double patenting as being unpatentable over claims 41-43, 44, 45, 48-50, 53, 54, 55-58, 60 of co-pending Application No. 11/296,644 in view of Goodchild et al. 1990 Bioconjugate Chemistry volume 1, p. 165-187 and Draper et al., 1991, WO 91/12811.

Although applicant disagrees with the rejection, the limitations of claim 36 have now been incorporated into the independent claim 28 in order to advance prosecution. Claim 36 was not rejected on the ground of nonstatutory double patenting in view of US Application No. 11/296,644. Thus it is requested that the rejection be withdrawn.

Claims 28-33, 35, and 37 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 19-22, 32, 33, 35, 50-53, 63-64, 66, 81, 82, 86, 87, 97, 98, 102, 103 of copending Application No. 10/613916 in view of Goodchild et al., 1990, Bioconjugate Chemistry volume 1, p. 165-187 and Oberhauser et al. 1992 Nucleic Acids Research vol. 20 p. 533-538 and Draper et al., 1991, WO 91/12811.

Although applicant disagrees with the rejection, the limitations of claim 36 have now been incorporated into the independent claim 28 in order to advance prosecution. Claim 36 was not rejected on the ground of nonstatutory double patenting in view of US Application No. 10/613916. Thus it is requested that the rejection be withdrawn.

Claims 28-33, 35 and 42 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-32 of copending Application No. 11/645,106 in view of Goodchild et al. 1990 Bioconjugate Chemistry volume 1, p. 165-187 and Oberhauser et al. 1992 Nucleic Acids Research vol. 20 p. 533-538 and Draper et al, 1991, WO 91/12811.

Although applicant disagrees with the rejection, the limitations of claim 36 have now been incorporated into the independent claim 28 in order to advance prosecution. Claim 36 was not rejected on the ground of nonstatutory double patenting in view of US Application No. 11/645,106. Thus it is requested that the rejection be withdrawn.

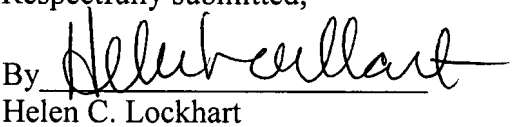
CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Dated: August 22, 2007

Respectfully submitted,

By 

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